

AMENDMENTS TO THE SEQUENCE LISTING

A paper copy of the "Sequence Listing", a computer-readable form in compact disc format, a the required statements are provided herewith.

REMARKS**1. Status of the Claims**

Claims 18-26 are pending in the present application. Claim 24 remains withdrawn. Claims 18 and 21 have been amended to overcome the rejections under 35 USC 112, second paragraph, and 35 USC 102. Additionally, claim 21 has been amended to overcome the objection at page 2, item 5 of the Office Action. Claim 22 has also been amended in response to the rejection under 35 USC 112, first paragraph. The amendment to claim 22 is supported by the specification at Example 8. No new matter has been entered.

At the outset, Applicants would like to point out that new claims 25 and 26 have been added directed to the DNA related to the amino acid sequence of SEQ ID Nos. 19 and 20, respectively. SEQ ID Nos. 19 and 20 recite the respective amino acid sequences of the translated nucleic acid sequence of SEQ ID Nos. 1 and 12, and are supported by the specification at page 5, third paragraph as amended in the amendment filed on September 19, 2005. An amended sequence listing, a copy of the amended sequence listing on compact disc, and required statements are enclosed herewith. Applicants believe claims 25 and 26 should be examined with the rest of the claims in this application, because claims 25 and 26 share a common core which is the amino acid sequence shown in SEQ ID No. 19 and 20. In the parent application, 08/568,310, now US 5,976,832, upon which this divisional application is based, a requirement for restriction under 35 USC 121 was made by the Examiner between SEQ ID No. 1 and SEQ ID No. 12. In the restriction requirement dated August 7, 1997 of the parent application, the Examiner found that:

This application [USSN 08/568,310] contains claims directed to the following patentably distinct species of the claimed invention...(3) the DNA of SEQ ID NO: 1; (4) the DNA of SEQ ID NO: 12.

Applicants point out that SEQ ID No. 1 and SEQ ID No. 12 directly correspond to their respective amino acid sequences in SEQ ID No. 19 and SEQ ID No. 20. Accordingly, Applicants are entitled to include claims 25 and 26 in a divisional application of the parent application.

An interference was declared between US 5,976,832 and US application no. 08/761,289 in Interference No. 105,501. Claim 1 of US 5,976,832 contains both SEQ ID Nos. 19 and 20. The claims are added in this application, because SEQ ID No. 19 in claim 25 and SEQ ID No. 20 in claim 26 were found to be patentably distinct by the Examiner in the parent application as indicated above. Therefore, both sequences have been separated in this application as two separate claims. Upon allowance of these claims, Applicants will request the claims to be made part of Interference No. 105,501.

Applicants believe the amendments to the claims overcome the rejections under 35 USC 112 and 35 USC 102, and will be entered and made of record, and because this amendment is filed with an RCE, a showing as required under 37 CFR 1.116 is believed to be not required.

II. Objection to claim 21

The Examiner objected to claim 21 at item 5 of the Office Action for being an improper multiple dependent claim. The claim has been amended so that it is no longer dependent on claim 19, but it is respectfully pointed out that the antibody recited in claim 21 is in reference to the monoclonal antibody in claim 19.

Due to the dependency issue in claim 21, the Examiner said that "the claim has not been further treated on the merits". However, the Examiner refers to claim 21 in the rejection under 35 USC 112, second paragraph, at item 9A of the Office Action. Nevertheless, claim 21 has been amended accordingly in response to both the objection and to the rejection under 35 USC 112, second paragraph, which is discussed herein.

III. Claim rejections under 35 USC 112, second paragraph

The rejection of claims 18-20 and 22-23 is respectfully traversed. It is noted that even though claim 21 is not recited in the rejection, the Examiner is examining claim 21 on its merits. The Examiner found the parenthesis in claim 21 to be indefinite. The claim has been amended accordingly and is believed to be definite. The Examiner found claims 18 and 21 to be indefinite with respect to the amino sequence in reference to SEQ ID Nos. 1 and 12. Claims 18 and 21 have been amended accordingly, and are believed to be definite. Accordingly, it is respectfully requested that this rejection under 35 USC 112, second paragraph, be reconsidered and withdrawn.

IV. Claim rejections under 35 USC 112, first paragraph

The Examiner rejected claim 22 for lack of enablement. At the first paragraph of item 12 of the Office Action, the Examiner did not find enablement for "a diagnostic agent for inflammatory diseases, 'neoplastic diseases', dermatosis or 'blood diseases' which comprises an antibody of claim 18, in claim 22.

In this regard, the rejection is respectfully traversed. Claim 22 has been amended to recite the "blood diseases of PMN (polymorphonuclear leukocytes), macrophages and these lineages". Moreover, Applicants refer the Examiner to the specification starting at page 24, line 25 to page 25, line 5, which recites:

For example, an antigen specifically present in cancerous cells may be useful as a marker for tumor diagnosis. Also, antigens abundantly present in cell groups involved in inflammation, such as neutrophils, leak out into the blood as inflammation progresses, and thus their blood concentrations may be useful as markers for diagnosis of inflammation. Furthermore, antigens which are abnormally expressed in connection with skin diseases may be used as markers for those diseases.

Thus, assay systems for the above-mentioned calcium-binding protein or fragments thereof may be used in diagnostic agents to yield useful information as an inflammatory disease marker, a neoplastic disease (especially epidermoid carcinoma of the skin, esophagus, respiratory tract, cervix, etc.) marker, a skin disease marker or a blood disease marker, for screening of patients during examinations, specifying the nature of diseases, monitoring the effects of treatment, etc.

Additionally, the specification starting at page 39, line 33 to page 40, line 18, discloses the expression of CAAF1, and page 40, line 9 recites:

Also, the differences of cancer cells and normal cells in immunoreactivities against the anti-CAAF1 antibody suggest the usefulness of the anti-CAAF1 antibody as a diagnostic agent for cancer (particularly squamous-cell carcinoma of the skin, oral cavity, esophagus, respiratory organs and cervix). In addition, the immunoreactivity of neutrophils and macrophages against anti-CAAF1 antibody further suggests additional usefulness of the anti-CAAF1 antibody as a diagnostic agent for various inflammatory diseases

Based on the above, it should be clear that claim 22 does not suffer for lack of enablement, and a person skilled in the art would find claim 22 enabling in view of the specification.

In addition, a separate paper will be enclosed by the Applicants in the form of a Declaration to support enablement for claim 22.

Accordingly, it is respectfully requested that this rejection under 35 USC 112, first paragraph, be reconsidered and withdrawn.

V. Claim rejections under 35 USC 102

The rejection of claims 18-19 and 22-23 under 35 USC 102(b) in view of Guignard et al. is respectfully traversed. The rejection of claims 18-20 and 22-23 under 35 USC 102(b) in view of Kelly et al. is respectfully traversed.

Applicants submit there is no teaching in either reference of an antibody which is "specific to a calcium-binding protein comprising an amino acid sequence shown in SEQ ID. No. 19 or 20, or encoded by a nucleic acid sequence shown in SEQ ID NO: 1 or 12." Nowhere is there any teaching of a nucleic acid or amino acid sequence in either Guignard or Kelly nor has the Examiner made any allegation of teaching of the sequences. Both references just describe the antibodies and proteins, but nowhere is there any mention of the antibodies specific to the respective sequences. The Examiner uses Yamamura to help support the argument, and while it is not being relied on for the actual anticipation rejection, the reference itself is from 1996. Applicants point out that this application claims priority to its parent which issued as US 5,976,832 and was filed on December 6, 1995 which ultimately claims priority to JP 7-045564 and JP 7-070468 were filed on March 6, 1995. Therefore, Applicants believe that Yamamura cannot be used as a reference under this section of the statute.

Moreover, SEQ ID Nos. 19 and 20 have been found both novel and nonobvious as evidenced by US Patent No. 5,976,832, which is the parent to this application. Therefore, because the sequences underlying claims 18-23 are novel and nonobvious, Applicants submit that claims 18-23 of this application are also novel and nonobvious.

Accordingly, it is respectfully requested that these rejections under 35 USC 102(b) be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing amendments to the claims and remarks, it is respectfully submitted that the present invention as defined in claims 18-23 and 25-26 is in full compliance with all the statutory requirements of Title 35 USC, and, therefore, it is earnestly requested that the Examiner's rejections be withdrawn and that the pending claims be passed to issue.

Respectfully submitted
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CERTIFICATE OF MAILING

I hereby certify that this *Amendment* is being deposited with the United States Postal Service via First Class Mail addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 30, 2006.

